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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,351	07/29/2003	Claes Gustafsson	MXGNP004X1/0311.310US	6357

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EXAMINER	
SKIBINSKY, ANNA	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,351	GUSTAFSSON ET AL.	
	Examiner	Art Unit	
	Anna Skibinsky	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *15 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) *1-75 and 82-100* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/05/06, 9-15-06, 10-24-06*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Applicants

Claims 1-75 and 82-100 are withdrawn. Claims 76-81 are under examination.

Objections to the Specification

Applicant's amendment to the specification filed 9/15/2006 is sufficient to over come the objection in the Office Action filed 6/15/2006.

Claim Rejections - 35 USC § 101

Claims 76-81 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 76-81 are drawn to a process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be

"tangible," the process must produce a real world result . Furthermore, the claim must be limited only to statutory embodiments.

Claims 76-81 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or other computer on a network or outputted to a user, or by including a physical transformation.

Reply to Arguments

Applicant's arguments filed 9/15/2006 have been fully considered but they are not persuasive.

Applicants argue (Remarks, page 22) the practicality and usefulness of the claimed invention.

The non-statutory rejection is maintained wherein the instant claims are not "useful, concrete, and tangible" in accordance to the PTO Guidelines. Reciting a useful method does not meet the criteria of being "useful, concrete, **and** tangible." For example, a process of computer program that outputs a result to a user would be considered statutory.

Said claims are toward a computer implemented method for the identifying of nucleotides for variation in a sequence to impact a desired activity. The method requires receiving data and an algorithmic process carried out by a computer program product, however the data is nontheless manipulated within a computer (i.e. generating an

optimized protein variant library" without a physical manifestation. There is no visual displaying of results, transfer of data from a processor to a memory and no physical sample comprising sequences to be analyzed, nor is any result output to the user. Thus, these claims are non-statutory and do not produce a result which meet the standard of being concrete, tangible and useful.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent; except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 76-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (US Pub. No. 2001/0051855; filed Feb. 16, 2001; claiming priority date Feb. 16, 2000).

3. The instant application pertains to a method for identifying amino acid residues for variation in a protein variant library. The identifying entails the characterization of a training set of protein variant sequences and determining which amino acids in the sequence have the greatest impact on the activity of the sequence.

4. Claim 76, step (a) recites data providing activity and nucleotide sequence information form each protein variant in a training set.

5. Wang et al. teach providing a parent sequence with properties of interest with residues that have a structural tolerance selected. Mutant polymers (i.e. variants) are created and then screened for properties of interest (i.e. activity) (paragraph 0023).

6. Claim 76, step (b) recites developing a model that predicts activity as a function of nucleotide types and position in the sequence.

7. Wang et al. teach identifying structurally tolerant residues in a polymer sequence where the mutation of the residues with high tolerance produce sequences with improved activity (paragraphs 0021, lines 10-22; and 0025). The tolerance is calculated for polymers of nucleic acids (paragraph 0132).

8. Claim 76, step (c) recites ranking positions in a nucleotide sequence or types at specific positions in order of impact on the desired activity.

9. Wang et al. teach quantifying the fitness (stability) of a sequence so that each amino acid will have a particular fitness value. Fitness is characterized as the extend to which a particular property (i.e. desired activity) of a polymer is optimized (paragraph 0083 to 0084).

10. Claim 77, step (d) recites ranking to identify nucleotides that are to be varied to impact the desired activity.

11. Want et al. teaches a method for selecting residues with structural tolerance for mutation to improve the certain properties of the sequence (paragraphs 0022 and 0083). Mutation of residues with structural tolerance lead to desired properties (paragraph 0021).

12. Claim 77 recites varying nucleotides which are codons.

13. Wang et al. teach the mutation of codons (paragraph 0014) and that the prior art is applied to polymers of nucleic acids (paragraph 0021) where genes can be modified directly or indirectly (paragraphs 150 and 154).

14. Claim 78 recites that the activity is a function of expression of nucleic acids.

15. Wang et al. teach the modification of parent amino acid sequences and expressing gene expression systems (paragraph 0154).

16. Claims 79-81 recite the method steps of claims 76-78 carried out by a computer program product.

17. Wang et al. teach the use of a computer system to carry out the described invention (Abstract; and paragraphs 160-171).

REPLY TO ARGUMENTS

18. Applicant's arguments filed 9/15/2006 have been fully considered but they are not persuasive.

19. Applicants argue (Remarks, page 23, lines 3-5 and lines 22-23) that the teachings of Wang et al. do not develop "a sequence activity model" from "a training set of a protein variant library" and that the expressions of Wang et al. are not "developed from a *training set*."

20. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Independent claims 76 and 79 recite "from the data, developing a sequence activity model," (claim 76, line 7) wherein the data is data

"characterizing a training set of a protein variant library" (claim 76, line 4). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

21. Furthermore, a definition of a "training set" is not provided in the specification, while a possible example (specification, page 13, lines 2-6) includes training set data with "a complete or partial residue sequence" and/or "an activity" value which fits the concept of providing a parent sequence to generate mutant polymers that are then selected based on properties of interest and made into the parent sequence in the next evolutionary step (paragraph 0023). As reiterated in the above rejection, this reads on the claim 76, line 4, limitation of "receiving data characterizing a training set."

22. Applicants argue (page 24, lines 7-8) that Wang et al. only teaches "fitness" which fails to suggest ranking positions in a nucleotide sequence as applied to "individual amino acids or nucleotides".

23. In response to applicant's argument that the references fail to show certain features of applicant's invention, (i.e. ranking positions of individual amino acids or nucleotides) it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 76, step b, recites predicting activity "as a function of nucleotide types and corresponding position" in the sequence, and claim 76, step c, recites "using the sequence activity model to rank positions in a

nucleotides sequence and/or nucleotide types at specific positions ..." The recited limitation are not limited to the fitness of any one amino acid or nucleotide at a specific position (i.e. individual amino acids or nucleotides) and encompass determining activity for groups of nucleotides either adjacent or even separated at a specific location in a sequence.

Conclusion

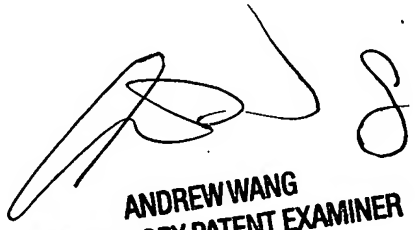
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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